

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of claims:

Claim 1. (Currently amended) A pharmaceutical composition for topical administration, said composition consisting of:

at least 5% by weight, based on the total weight of the composition, of minoxidil or a pharmaceutically acceptable minoxidil salt selected from the group consisting of minoxidil acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil lactate, as sole hair-growing active present in the composition, and wherein the minoxidil or salt thereof is not encapsulated;

an acid in an amount to substantially completely solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt;

a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 9:1 to 1:9 by volume;

a co-solvent selected from one or more of the group consisting of aromatic alcohols and polyhydric alcohols, wherein when the co-solvent comprises propylene glycol, the propylene glycol is present in an amount of less than 10% by weight;

optionally one or more penetration agents selected from the group consisting

of dodecanol, oleyl alcohol, an amine, a carboxylic acid, an ester, azone, N-methyl pyrrolidone, a bile salt, urea, and mixtures thereof; and

optionally one or more excipients selected from the group consisting of a higher alcohol, a vitamin, a preservative, a buffer, a stabilizer, a propellant, a hair generating agent, an antibacterial agent, a refrigerant, an amino acid, an oil component, a perfume, an antioxidant, a UV absorber, a dye, a humectant, a thickener, a gelling agent, and a color additive,

~~wherein the final product of the pharmaceutical composition is selected from the group consisting of a solution, lotion, ointment, mousse, a foam that breaks with shear, spray, aerosol, shampoo, conditioner, gel, cream and paste wherein the apparent pH of the final product is in the range of from approximately 5.0 to 7.0, and wherein the pharmaceutical composition is actuated with a propellant to form a foam or mousse.~~

Claim 2. (Cancelled)

Claim 3. (Previously presented) The pharmaceutical composition according to claim 1, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from at least 5 to 25% by weight, based on the total weight of the pharmaceutical composition.

Claim 4. (Previously presented) The pharmaceutical composition according to claim 3, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from 7.5 to 12% by weight, based on the total weight of the pharmaceutical composition.

Claims 5-7. (Cancelled)

Claim 8. (Currently Amended) The pharmaceutical composition according to claim 2 1, wherein the acid is acetic acid or lactic acid.

Claim 9-11. (Cancelled)

Claim 12. (Previously presented) The pharmaceutical composition according to claim 1, wherein the water is present in an amount no greater than approximately 60% by weight based on the total weight of the composition.

Claim 13. (Previously presented) The pharmaceutical composition according to claim 1, wherein the co-solvent is an alkylene glycol.

Claim 14. (Previously presented) The pharmaceutical composition according to claim 13, wherein the alkylene glycol is selected from one or more of the group

consisting of glycerol, 1,3-butylene glycol and propylene glycol.

Claim 15. (Previously presented) The pharmaceutical composition according to claim 1, wherein the acid is present at a level that provides at least 0.01 Normal acid.

Claim 16. (Previously presented) The pharmaceutical composition according to claim 1, wherein the acid is present in an amount equal to or greater than the amount of the minoxidil in Normal amounts.

Claims 17-18. (Canceled)

Claim 19. (Previously presented) The pharmaceutical composition according to claim 1, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

Claim 20. (Canceled)

Claim 21. (Currently amended) A method for the treatment of hair loss and related indications in humans, comprising the steps of:

providing a pharmaceutical composition, consisting of

at least 5% by weight, based on the total weight of the composition, of minoxidil or a pharmaceutically acceptable minoxidil

salt selected from the group consisting of minoxidil acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil lactate, as sole hair-growing active present in the composition, and
wherein the minoxidil or salt thereof is not encapsulated;

an acid in an amount to substantially completely solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt;

a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 9:1 to 1:9 by volume;

a co-solvent selected from one or more of the group consisting of aromatic alcohols and polyhydric alcohols, wherein when the co-solvent comprises propylene glycol, the propylene glycol is present in an amount of less than 10% by weight;

optionally one or more penetration agents selected from the group consisting of dodecanol, oleyl alcohol, an amine, a carboxylic acid, an ester, azone, N-methyl pyrrolidone, a bile salt, urea, and mixtures thereof; and

optionally one or more excipients selected from the group consisting of a higher alcohol, a vitamin, a preservative, a buffer, a stabilizer, ~~a propellant~~, a hair generating agent, an antibacterial agent, a refrigerant, an amino acid, ~~an oil component~~, a perfume, an

antioxidant, a UV absorber, a dye, a humectant, a thickener, a gelling agent, and a color additive, and wherein the apparent pH of the final product is in the range of from approximately 5.0 to 7.0,
actuating the pharmaceutical composition with a propellant to form the pharmaceutical composition as a foam or mousse; and
applying topically to the human scalp a therapeutically effective amount of the pharmaceutical composition foam or mousse.

Claim 22. (Cancelled)

Claim 23. (Previously presented) The method according to claim 21, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

Claim 24. (Previously presented) The method according to claim 21, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from at least 5 to 25% by weight, based on the total weight of the composition.

Claim 25. (Cancelled)

Claim 26. (Previously presented) The pharmaceutical composition according to claim 1, wherein the lower alcohol is ethanol.

Claims 27-28. (Cancelled)

Claim 29. (Previously presented) The pharmaceutical composition according to claim 26, wherein the ratio of water to ethanol is approximately 1:1 to 1:3 by volume.

Claims 30.-138. (Canceled)

Claim 139. (New) The pharmaceutical composition according to claim 8, wherein the acid is lactic acid.

Claim 140. (New) The pharmaceutical composition according to claim 14, wherein the alkylene glycol is glycerol.

Claim 141. (New) The pharmaceutical composition according to claim 1, wherein the higher alcohol is present in the pharmaceutical composition and is selected from the group consisting of cetyl alcohol, stearyl alcohol, and combinations thereof.

Claim 142. (New) The pharmaceutical composition according to claim 1, wherein the stabilizer is present in the pharmaceutical composition and is Polysorbate 60.

Claim 143. (New) The pharmaceutical composition according to claim 1, wherein the propellant is selected from the group consisting of one or more hydrocarbons, dimethyl ether, and a chlorofluorocarbon.

Claim 144. (New) The pharmaceutical composition according to claim 143, wherein the propellant is one or more hydrocarbons.

Claim 145. (New) The pharmaceutical composition according to claim 1, wherein the antioxidant is present in the pharmaceutical composition.

Claim 146. (New) The method according to claim 24, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from 7.5 to 12% by weight, based on the total weight of the pharmaceutical composition.

Claim 147. (New) The method according to claim 21, wherein the acid is acetic acid or lactic acid.

Claim 148. (New) The method according to claim 147, wherein the acid is lactic acid.

Claim 149. (New) The method according to claim 21, wherein the water is present in an amount no greater than approximately 60% by weight based on the total

weight of the composition.

Claim 150. (New) The method according to claim 21, wherein the co-solvent is an alkylene glycol.

Claim 151. (New) The method according to claim 150, wherein the alkylene glycol is selected from one or more of the group consisting of glycerol, 1,3-butylene glycol and propylene glycol.

Claim 152. (New) The method according to claim 151, wherein the alkylene glycol is glycerol.

Claim 153. (New) The method according to claim 21, wherein the acid is present at a level that provides at least 0.01 Normal acid.

Claim 154. (New) The method according to claim 21, wherein the acid is present in an amount equal to or greater than the amount of the minoxidil in Normal amounts.

Claim 155. (New) The method according to claim 21, wherein the lower alcohol is ethanol.

Claim 156. (New) The method according to claim 155, wherein the ratio of water to ethanol is approximately 1:1 to 1:3 by volume.

Claim 157. (New) The method according to claim 21, wherein the higher alcohol is present in the pharmaceutical composition and is selected from the group consisting of cetyl alcohol, stearyl alcohol, and combinations thereof.

Claim 158. (New) The method according to claim 21, wherein the stabilizer is present in the pharmaceutical composition and is Polysorbate 60.

Claim 159. (New) The method according to claim 21, wherein the propellant is selected from the group consisting of one or more hydrocarbons, dimethyl ether, and a chlorofluorocarbon.

Claim 160. (New) The method according to claim 159, wherein the propellant is one or more hydrocarbons.

Claim 161. (New) The method according to claim 21, wherein the antioxidant is present in the pharmaceutical composition.